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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,338	08/07/2001	James Tobin	22058-516-DIV-CON	3551

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,338

Applicant(s)

TOBIN, JAMES

Examiner

Prema M Mertz

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,39-53 and 55-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 39-53, 55-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-17, 19-38, 54 have been canceled previously. Claims 18, 39-53, 55-65 are under consideration.
2. Receipt of applicant's arguments and amendments filed on 2/26/2004 is acknowledged.
3. Applicant's arguments filed on 2/26/2004 have been fully considered but were non-persuasive. The issues remaining are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

5. Claims 18, 39-53, 55-65 are rejected under 35 U.S.C. § 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action (9/26/03).

Applicant argues that the claims have been amended to specify that the antibody binds to an epitope within a human IL-11 receptor polypeptide and claims 18, 58 and 62 have been amended to recite that the recited antibody specifically reacts with a human IL-11 receptor protein. Furthermore, Applicant argues that the claims further require that the human IL-11R protein "comprises" an amino acid sequence from SEQ ID NO:2 selected from the group consisting of amino acids 26 to 111, amino acids 112 to 365, amino acids 366 to 390, and amino acids 391 to 422. Thus, Applicant argues that the presently claimed antibody expressly excludes antibodies that bind to a polypeptide or moiety other than an IL-11 Receptor polypeptide. However, contrary to Applicant's arguments, the claims fail to expressly exclude antibodies that bind to a polypeptide or moiety other than an IL-11 receptor polypeptide.

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Claim 18, for example, still recites "wherein said IL-11R protein comprises....." and the recitation of the limitation "comprises" permits the instant claims to encompass an antibody which binds to an epitope that is not contained within SEQ ID NO:2. It was well known in the art long before the instant invention was made to express a recombinant protein as part of a fusion protein "comprising", in addition to the amino acid sequence of a desired protein, an antigenic tail such as a FLAG epitope, a polyhistidine tail, keyhole limpet hemocyanin or a protein A fragment to facilitate the purification of the desired protein, as disclosed on page 23, lines 5-17, of the instant specification. The text on page 23 of the instant specification encompasses a human IL-11R polypeptide, which can include a "tag" (hapten). Therefore, because of the presence of the term "comprises" in the instant claims, the claims encompass any antibody which can bind to any epitope which can be expressed as a portion of a polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:2 and, therefore they essentially encompass any antibody which can bind to any polypeptide or protein comprising a "tag". The instant specification, however, does not provide the guidance needed to produce an antibody, which binds to any epitope other than an epitope which is contained within SEQ ID NO:2 of the instant application.

Claim Rejections - 35 USC § 102

5. Claims 18, 39-53, 55-65 are rejected under 35 U.S.C. § 102(b) as being anticipated by the Giaever patent (4,054,646).

This rejection is maintained for reasons of record set forth at page 3 of the previous Office action (9/26/03).

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Applicant argues that independent claims 18, 58, and 62 have been amended to require that the recited antibody specifically reacts with a human IL-11R protein and that since Giaever does not describe antibodies to an IL-11R protein, therefore, it fails to describe all the features of the invention now claimed. Applicants also argue that Giaever additionally fails to disclose an antibody that binds to polypeptides that include the recited amino acid sequences, i.e. an amino acid sequence from SEQ ID NO:2 selected from the group consisting of amino acids 26 to 111, amino acids 112 to 365, amino acids 366 to 390, and amino acids 391 to 422.

However, contrary to Applicants arguments, Giaever still describes the invention now claimed, and anticipates the instant claims because the claims have been amended to recite, "comprises an amino acid sequence", which claims encompass an antibody to any hapten or tag, including the KLH tag, which was bound by the antibody of Giaever prior to the time of the instant invention. The reference discloses the KLH antibody (column 18, lines 5-13) meeting the limitations of claims 18, 39-53, 55-65. Therefore, the KLH antibody of the reference anticipates instant claims 18, 39-53, 55-65.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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March 17, 2004